VA Cooperative Studies Program (CSP)
Solicitation for CSP Planning Requests
Research Priority Announcement
October 24, 2001

Health Services Research and Development (HSR&D)/Cooperative Studies Program
Joint Request for Clinical Trial Applications

The VA HSR&D and CSP Programs have identified the following content areas for the conduct of multi-site, phase III (and late phase II) **clinical trials** of innovative clinical and/or systems interventions. A prerequisite for all applications is documented evidence that sufficient preliminary research has been completed (through small studies or trials) that demonstrates safety, efficacy and ability to operationalize/standardize the proposed therapies, interventions or technologies. Although the areas below have been identified as high priority, they are not exclusive. Areas of priority include trials designed to:

1. Evaluate interventions that improve care for patients with chronic illness (e.g. chronic heart failure, diabetes, hypertension, COPD, etc.). This may include interventions that:
    - randomize patients to disease management models that exist in primary or specialty care
    - evaluate the influence of various physician extenders
    - evaluate the influence of condition specific disease management strategies
    - evaluate the relationships between generalist and specialist physicians

2. Evaluate interventions that enhance equitability in access and utilization of health care (especially in cancer screening and treatment, cardiovascular procedures and treatments, diabetes, HIV, and immunizations).

3. Evaluate the effectiveness of innovative methods of health education/information for VA patients and/or their families.

4. Evaluate the effectiveness of interventions to improve patient safety by reducing common types of medical errors (e.g., adverse drug events, hospital-acquired infections, and falls). Studies are encouraged to address how changes in organization, management, communication, or scheduling affect patient safety.

5. Evaluate interventions to implement VA-approved, evidence-based practice guidelines to determine which incentives, sanctions, educational interventions, quality assurance checks, or administrative rules contribute to effective guideline implementation in VA.

6. Interventions to improve the quality and cost-effectiveness of substance abuse treatment. Examples include:
    - buprenorphine for opiate dependence in the primary care setting
    - interventions to improve the continuity and duration of substance abuse care

- enhancement of the integration of substance abuse treatment in primary and specialty care
- brief intervention for substance abuse disorders in primary care settings
- effectiveness of Zyban in smoking cessation

Application Process

- Interested investigators should contact Joe Gough, MA, Cooperative Studies Program Analyst at (202) 273-8248 to request a copy of Instructions for Submission of a CSP Planning Request. CSP Planning Requests may be submitted at any time. Please indicate on the Planning Request "Submitted for the HSR/CSP Joint Clinical Trials Solicitation".

- Submit five copies of the CSP Planning Request and curriculum vitae to: VA Headquarters, Cooperative Studies Program (125B), 810 Vermont Avenue, NW, Washington, DC 20420. All CSP Planning Requests will be reviewed by ad hoc experts in the field of the research proposed. Notification of the Planning Request review disposition will be provided in approximately one month.

- Investigators with an approved CSP Planning Request will be assigned by VA CSP Headquarters to one of the four VA Cooperative Studies Coordinating Centers for technical assistance and guidance in development of a full study protocol.

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Chief Research and Development Officer